Review Summary

May 19, 2026

Pharmaceuticals and Medical Devices Agency

The following is the summary of the review of the following medical device submitted for marketing approval conducted by the Pharmaceuticals and Medical Devices Agency (PMDA).

Classification	:	Instrument & Apparatus 21, Organ function testing apparatus
Term name	:	Diagnostic assistant device for pathological whole slide image
Brand name	:	E1000 Dx Digital Pathology Solution
Applicant	:	PHC Corporation
Date of application	:	May 29, 2025
Date of approval	:	February 19, 2026
Application classification	:	☐New medical device ☒Improved medical device (with clinical data) ☐Improved medical device (without clinical data)
New approval / partial change	:	☒New Approval ☐Partial Change
Review category	:	☐Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry ☐Cardiopulmonary Circulation ☐Dentistry and Oral Medicine ☐Gastroenterology, Genitourinary, and Reproductive Medicine ☐Ophthalmology and Otorhinolaryngology ☐Orthopedic and Plastic Surgery ☒Robotics, IoT, and other devices (not classified as other categories) ☐Program D1 ☐Program D2
Items warranting special mention	:	☐Designated as medical devices with high medical need ☐Designated as specific-usage medical device ☐Application in accordance with conditional early approval system for medical devices (Type 1)

☐Application in accordance with conditional early approval system for medical devices (Type 2: "Physical operation of items' extrapolative and inclusive approval" (Phoenix))

☐Application in accordance with the notification on pre- and post-market rebalancing (☐1st step ☐2nd step)

☐Application in accordance with "Improvement design within approval for timely evaluation and notice" (IDATEN)

☐Designated as orphan medical device

☐Application in accordance with the 0929 notification

☐Other ( )

Expert Discussion : ☐Yes ☒No

1. Submitted data

(1) Background of the development

This product is a diagnostic assistant device for pathological whole slide image used for assisting pathologists in evaluation and diagnosis through creation, storage and display of high magnification images of whole pathological slide samples. The purpose of development of this product is to launch a product capable of loading up to 1,000 pathological slide samples with intended use, usage, and performance equivalent to other company's approved products.

(2) Non-clinical Data

The following non-clinical data were submitted (data items are based on applicant submission data).

- Electrical safety and electromagnetic compatibility: data indicating conformity with IEC 61010-1:2010+AMD1:2016, IEC 61010-2-101:2018, IEC 61326-1:2021, IEC 61326-2-6:2021
- Performance: studies conducted in accordance with FDA guidance "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices (April 20, 2016)"
- Software Lifecycle Process: data on conformity to IEC 62304:2006/AMD:2015
- Usability Engineering: data on conformity to IEC 62366-1:2015+A1:2020
- Cybersecurity: data on conformity to IEC 81001-5-1:2021

(3) Clinical Data

The applicant submitted a clinical evaluation report putting together "A Multi-center Blinded Randomized Pivotal Study for Evaluating Performance of the Epredia E1000 Dx Digital Pathology System" conducted in the United States. The outline of this clinical study is as follows (the clinical results section of the package insert is cited, and table numbers are modified as necessary).

1. Objectives

The primary objective of this study was to verify that diagnosis using digital images (Whole Slide Image, WSI) of surgical pathology tissue slides is non-inferior to diagnosis using optical microscopy (Glass). For the above verification, the difference in major discordance rates between MD and MO was compared and evaluated against SD based on the original definitive results (SD) using optical microscopy.

- Sign-out Diagnosis (SD): Diagnostic results previously made by pathologists using optical microscopy and obtained using other clinical information
- Manual digital (MD): Diagnostic results newly performed using WSI images
- Manual optical (MO): Diagnostic results newly performed using optical microscopy

2.Study design

The difference in major discordance rates between MD and MO was compared and evaluated against SD. The acceptance criteria were as follows.

・MD: Major discordance rate between WD and SD … less than 7%, 95% confidence interval

・MD-MO: Difference between the above two major discordance rates … less than 4%, 95% confidence interval

3. Test method

Multiple pathologists diagnosed 1,299 cases obtained from 3 different facilities using WSI and Glass, and each was compared with SD.

4. Test result

Table 1 shows the overall major discordance rates for MD and MO.

Table 1: Major discordance rates in MD and MO

	MD: Major Discordance Rate			MO: Major Discordance Rate			Difference MD-MO	
	N:	%	95% CI	N:	%	95% CI	%	95% CI
Observed	3897	2.54%		3881	2.65%		-0.11%	
Modeled		2.51%	(2.26%; 2.79%)		2.59%	(2.29%; 2.82%)	-0.15%	(-0.40%; 0.41%)

Table 2 shows the major discordance rates by main anatomical region.

Table 2: Detailed list of major discordance rates observed by anatomical region

Anatomical Region	MD Major Discordance		MO Major Discordance		Difference MD-MO
	N:	%	N:	%	%
Adrenal	75	1.3%	75	0.0%	1.3%
Anal	75	4.0%	75	2.7%	1.3%
Appendix	60	0.0%	60	0.0%	0.0%
Bladder	342	3.2%	342	2.3%	0.9%
Brain	207	4.3%	207	2.9%	1.4%
Breast	360	0.6%	357	1.1%	-0.6%
Colo-Rectal	282	0.0%	282	0.7%	-0.7%
Gall Bladder	60	5.0%	59	5.1%	-0.1%
GE Junction	150	2.0%	141	0.0%	2.0%
Gyn	357	7.3%	357	10.1%	-2.8%
Hernia/Peritoneum/Omentum	60	1.7%	60	3.3%	-1.7%
Kidney	135	4.4%	135	2.2%	2.2%
Liver/Bile Duct	135	1.5%	135	3.0%	-1.5%
Lung	210	2.4%	207	4.3%	-2.0%
Lymph Node	222	1.8%	222	3.2%	-1.4%
Pancreas	75	0.0%	75	0.0%	0.0%
Parathyroid	30	0.0%	30	0.0%	0.0%
Prostate	300	0.0%	300	0.0%	0.0%
Salivary Gland	75	2.7%	75	2.7%	0.0%
Skin	297	3.4%	297	1.7%	1.7%
Soft Tissue	90	1.1%	90	1.1%	0.0%
Stomach	210	2.4%	210	1.0%	1.4%
Thyroid	90	5.6%	90	7.8%	-2.2%

5. Conclusion

As summarized in Table 1, the major discordance rate between WSI (MD) and SD was observed to be 2.54% (99/3897), and the major discordance rate between Glass (MO) and SD was observed to be 2.65% (103/3881). The overall major discordance rates estimated by the generalized linear model were 2.51% (95% CI: 2.26%, 2.79%) for MD and 2.59% (95% CI: 2.29%, 2.82%) for MO. The estimated difference in major

discordance between MD rate and MO rate was calculated to be -0.15% (95% CI: -0.40%, 0.41%).

These results meet the acceptance criteria of this clinical study. Therefore, the WSI method using this product is considered to be non-inferior to conventional optical microscopy.

2. Review Results

PMDA concluded that efficacy and safety of the product could be largely explained in non-clinical studies. Considering that some clinical use experience is shown in the clinical evaluation report, PMDA concluded that the product could be approved.

<Intended Use>

The E1000 Dx Digital Pathology Solution is a system that assists pathologists in evaluation and diagnosis through creation, storage, and display of high-magnification images of whole pathological slide samples (pathological whole slide images).

This product is intended for use with pathological slide samples prepared from formalin-fixed paraffin-embedded (FFPE) tissue and is not intended for use with frozen section samples, cytological samples, or non-FFPE blood samples.